

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:)
) CA No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY AVERAGE) CA No. 08-11200-PBS
WHOLESALE PRICE LITIGATION) Pages 1 - 33
)

MOTION HEARING

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
November 8, 2011, 3:00 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617) 345-6787

1 A P P E A R A N C E S:

2
3 MARK ALLEN KLEIMAN, ESQ., Attorney-At-Large,
4 2907 Stanford Avenue, Venice, California, 90292, for the
5 Relators.

6
7 TINA D. REYNOLDS, ESQ. and J. ANDREW JACKSON, ESQ.,
8 Dickstein Shapiro, LLP, 1825 Eye Street, NW, Washington, DC,
9 20006-5403, for Baxter Healthcare.

10
11 PETER E. GELHAAR, ESQ., Donnelly, Conroy & Gelhaar, LLP,
12 One Beacon Street, 33rd Floor, Boston, Massachusetts, 02108,
13 for Baxter Healthcare.

14
15 ALSO PRESENT: Jennifer Vankamp, Esq.
16 David J. Chizewer, Esq.
17 George B. Henderson, II, Esq.
18
19
20
21
22
23
24
25

P R O C E E D I N G S

THE CLERK: Court calls Civil Action 01-CV-12257,
In Re: Average Wholesale Price Litigation. Could counsel
please identify themselves for the record.

MR. KLEIMAN: Good afternoon, your Honor. Mark
Kleiman here for the relators. And with me in court today is
Jennifer Verkamp from Morgan Verkamp and David Chizewer from
Goldberg Cohen, two firms that are prepared, depending on the
outcome of this hearing, to associate in.

THE COURT: Thank you.

MR. JACKSON: Good afternoon, your Honor. Andy
Jackson, Dickstein Shapiro, for Baxter.

MS. REYNOLDS: And Tina Reynolds from Dickstein
Shapiro as well.

MR. GELHAAR: And Peter Gelhaar --

THE COURT: Peter Gelhaar I know from around here.

MR. GELHAAR: From around here.

THE COURT: You're a local counsel?

MR. GELHAAR: Yes, I am. It will be a learning
experience.

THE COURT: So I was informed before I came down here
that you are seeking to address multiple motions rather than
just the ones that are joined. Is that correct?

MR. JACKSON: Well, your Honor, I'm prepared to give
you the lay of the land, if you'd like.

1 THE COURT: All right.

2 MR. JACKSON: There is one motion that's set for
3 today, but I thought maybe review the bidding a little bit
4 because, frankly, I think a motion that is going to be joined
5 relatively soon we think is dispositive, and it might actually
6 moot today's argument. So if you'd like me to run through
7 that --

8 THE COURT: Aren't you all here from all over the
9 country? I mean, I'm going to do today's argument and then --
10 I have read the other motion, but it wasn't joined, so I don't
11 know if I'm prepared. Did you want to argue the second one
12 today having to do with the settlement agreement?

13 MR. KLEIMAN: No, we're not prepared to argue it
14 today, and it would be the subject of an opposition and
15 probably a 56(f) declaration as well.

16 THE COURT: Well, let's do this: I am not likely to
17 have a second oral argument, so maybe what you can do is at
18 least give me your positions. Then I'll take the written brief
19 when it comes in. All right, go ahead.

20 MR. JACKSON: All right, your Honor, we'll start then
21 with today's argument which relates to a first-to-file
22 argument. There are only two drugs left in this case for the
23 AWP False Claims Act claims. There are several employment/
24 wrongful discharge claims that we've not moved to dismiss. The
25 focus of the motions practice today and the opposition that

1 you're going to receive tomorrow relate to the AWP FCA. Our
2 argument today is regarding one of the two remaining drugs,
3 Recombinate, an antihemophilia drug. One of the two relators,
4 Mr. Hamilton, was deemed by you to be an original source for
5 that single drug in our prior motion to dismiss.

6 Since the time we filed those motions -- and the basis
7 of this motion is the Ven-A-Care case that came unsealed, I
8 guess about a year ago. The Ven-A-Care case specifically calls
9 out Recombinate as a drug that's the subject of that
10 litigation. That complaint identifies four separate same kind
11 of pricing theories that you've been listening to for ten
12 years. It identifies list price, wholesale net, direct price,
13 and wholesaler acquisition cost. It's the same theory: That
14 Baxter allegedly gave these prices to the compendia. They were
15 different than average wholesale price. That created a spread.
16 The spread caused impact, adverse impact to Medicare and
17 Medicaid. You know, it's the same marketing-the-spread theory.
18 In that set of briefing, the relators argue that their new case
19 was a new species of AWP case. I believe you rejected that
20 previously in argument, and I direct your attention to Pages 16
21 and 17 of that hearing transcript and what you said about this
22 alleged new species, and I'm happy to read it for you.

23 THE COURT: Sure. I'm getting older. I don't
24 remember what I've said, you know? You know, you can be seated
25 if you want and then --

1 MR. KLEIMAN: Thank you, thank you.

2 THE COURT: Thank you.

3 MR. JACKSON: So Mr. Kleiman argues that this is a new
4 species of AWP fraud. Your response is: "I know you're trying
5 to claim there's a new kind of AWP fraud, but, as I read it --
6 I've been dealing with these kinds of claims for ten years --
7 What is WAC? How does it differ from direct price? How does
8 it differ from list price? What are you marking up by
9 1.25 percent? -- it's not so new."

10 So, your Honor, we believe that this qui tam case, the
11 Ven-A-Care case that came out from under seal after fifteen
12 years of being under seal, directly deals with Recombinate. It
13 lists the same kind of AWP fraud about which you've been
14 dealing forever, and we believe, under the first-to-file bar,
15 the Court lacks jurisdiction over that.

16 THE COURT: And the first-to-file bar applies even
17 when something is under seal and they couldn't possibly have
18 known about it, they're just out of luck kind of thing. Even
19 if they've done everything that they can do to disclose, in
20 their view, a fraud, if somebody caught it first, it's tough
21 luck.

22 MR. JACKSON: Tough luck. The case law is, there are
23 no exceptions to this jurisdictional issue. And it's based
24 upon the notion that that first-to-file complaint, while
25 Mr. Kleiman may not have seen it, the Justice Department

1 certainly did, and it's designed to give the Justice Department
2 notice so they can decide whether to investigate. And the
3 Ven-A-Care, as you may remember, is a non-intervened case.
4 This case is a non-intervened case. So we think under the
5 first-to-file and this Circuit's Ortho decision, that the
6 Recombinate claims should be dismissed, and if the Recombinate
7 claims are dismissed, so should Mr. Hamilton. You previously
8 ruled that he was an original source, but to quote this Court,
9 it was a "close call." If his drug disappears, we think he
10 should disappear as well.

11 THE COURT: All right, thank you. And just to move us
12 one step further, are you going to be addressing the other drug
13 as well?

14 MR. JACKSON: I'm happy to do that, your Honor. The
15 summary judgment motion that we have filed addresses both
16 drugs.

17 THE COURT: And that's what you say hasn't been
18 opposed yet?

19 MR. JACKSON: They're filing their brief tomorrow, and
20 I think our reply brief is due the 23rd. Just to give you a
21 little flavor of what that pleading is, we have a settlement
22 agreement with Ven-A-Care. The Ven-A-Care plaintiffs signed
23 that settlement agreement in late September. The Justice
24 Department consented to that settlement agreement on October 3.
25 We signed it on the 5th and filed it on the 7th.

1 THE COURT: And that specifically lists Recombinate,
2 right?

3 MR. CHEFFO: That specifically lists -- and look for
4 it in Paragraph 2(e) of the settlement agreement -- it lists
5 all Baxter drugs, and then also specifically includes two
6 labeler codes, those two labeler codes, one of which covers
7 both Recombinate and Advate. So it's very broad release. It's
8 all Baxter drugs and then separately also calls out labeler
9 codes, and that's the same kind of structure that's been used
10 in a variety of the other non-intervened cases, that this is
11 kind of the form of the settlement agreement that's been
12 entered into.

13 So we argue in our papers that we have a full and
14 final settlement with the relators in Ven-A-Care, and with the
15 Justice Department, and we've paid. That takes care of the
16 drugs in this case.

17 THE COURT: Is it the exact same time period?

18 MR. JACKSON: The exact same time period.

19 THE COURT: So in a sense, this would take care of
20 everything, this agreement, right? So that's probably why I
21 should probably wait to even rule on the motion to dismiss till
22 I see a response. And then I understand you have another
23 argument with respect to the second drug.

24 MR. JACKSON: Well, but I also believe, in our papers,
25 in addition to the settlement agreement, we also address very

1 specifically this Court's rulings about the history and
2 knowledge of the government and how that would preclude a False
3 Claims Act case on these two drugs, the remaining drugs, the
4 hemophilia drugs. You will see in our papers that -- and I've
5 told you this before, your Honor, but it's just now teed up --
6 those two therapies, maybe different than any other AWP case
7 you've had, presents a very clear public record that talks
8 about cross-subsidization. It talks, the public record, it
9 talks about how the DOJ AWPs were released, and then HHS told
10 the governments not to use the DOJ AWPs for these two therapies
11 because there was inadequate reimbursement. So it's the best
12 cross-subsidization case that you've had.

13 More importantly, you will see our discussion of the
14 MMA. So we've got perfect storm. We've got MMA where you drew
15 many, many lines. The legislative history to the MMA
16 specifically talks about hemophilia drugs and how reimbursement
17 would not be reduced to 85 percent of AWP but remain at
18 95 percent, so that these other things that are required when
19 the hemophilia drugs are administered, it pays for that.

20 So we think, in addition to the settlement agreement,
21 we think the state today of the public record regarding these
22 therapies, both in terms of the investigations that took place
23 before 2001, in 2001 the AWPs, the perfect storm, and then in
24 2003 with the passage of the MMA, that we think, without more,
25 there is adequate evidence and an adequate record for you to

1 rule in favor of us on those defenses as well.

2 THE COURT: Well, let me ask you. On the release,
3 doesn't the complaint that's being released specifically list
4 Recombinate, or not?

5 MR. JACKSON: The complaint, the Ven-A-Care complaint
6 specifically identifies Recombinate. It was filed in 1995,
7 that complaint. Advate was not sold until late 2003, but the
8 release nonetheless covers all Baxter drugs. And again I
9 direct your attention to 2(e). It's a very, very broad
10 discussion of the drugs. It's a broad discussion of the
11 conduct.

12 THE COURT: How much money was exchanged?

13 MR. JACKSON: \$30 million.

14 THE COURT: And was there a specific consideration of
15 Advate?

16 MR. JACKSON: It was an all-in discussion, your Honor.
17 You know, I can't go into the specifics --

18 THE COURT: I understand that, but it's clear that
19 Recombinate must have been on the table because it was
20 mentioned in the complaint, but the rest of it seems like a
21 catch-all.

22 MR. JACKSON: Well, your Honor, again, it's very clear
23 about all drugs, and there's a reason for that, right? We've
24 been litigating this case or dealing with it since 1995, and
25 like any other defendant, we want peace. If we're going to pay

1 that kind of money to resolve a matter, we want peace across
2 the board.

3 THE COURT: For all drugs is your --

4 MR. JACKSON: All drugs, yes, your Honor.

5 THE COURT: All right, thank you.

6 Let me ask you this. You know, I was sort of working
7 with my law clerk diligently on the jurisdictional
8 first-to-file rule, and then I found out about this settlement.
9 I'm sure you found out about this settlement. Doesn't it just
10 resolve the whole thing? Put aside for a minute the
11 cross-subsidization issue and even the first-to-file issue. If
12 there's a complete global release, isn't that the end of it?

13 MR. KLEIMAN: Well, first of all, there's a great
14 question about whether this is in fact a complete global
15 release because the same -- first of all, the government never
16 signed onto a release of anything beyond what was alleged in
17 the Ven-A-Care complaint.

18 THE COURT: So at the very least, though, it resolves
19 Recombinate?

20 MR. KLEIMAN: Although I'm loathe to cite her as legal
21 authority, this is reminiscent of Sinead O'Connor's "I Cannot
22 Release What I Don't Have." There is a serious question --

23 THE COURT: I'm embarrassed to tell you I have no idea
24 who that is.

25 (Laughter.)

1 MR. KLEIMAN: She is an Irish pop rock singer popular
2 about fifteen or twenty years ago. I'm embarrassed to have
3 brought her up.

4 THE COURT: Oh, that's okay. I learned something.

5 MR. KLEIMAN: And she wrote a song called "I Cannot
6 Miss What I Don't Have." The reason I raise it is that your
7 Honor in another context had written very specifically about
8 how the history of this MDL makes it perfectly clear that each
9 drug has to be evaluated on its own. You can't have --

10 THE COURT: Okay.

11 MR. KLEIMAN: You can't have catchall claims or
12 omnibus claims or conclusory allegations. What the Ven-A-Care
13 complaint -- and I have the utmost respect for Mr. Brigg --
14 what the Ven-A-Care complaint does is say, "Well, it could
15 be --" and it lists the four factors my colleague mentioned.
16 "It could be any one of these. It could be a couple of these.
17 We don't know," and it gives a couple of examples, none of
18 which are biologics. It says nothing at all about the fact
19 that there's this whole different class of trade; specifically,
20 the non-charge-back wholesalers.

21 Yes, Ven-A-Care's complaint listed Recombinate. Yes,
22 the settlement agreement incorporates what is in the Ven-A-Care
23 complaint. We've got serious questions about whether or not
24 Ven-A-Care adequately pled a case about Recombinate, and that's
25 the case we intend to make to this Court.

1 THE COURT: I think that's a tough argument for you.
2 The government settled it, and they approved it, and it
3 included that drug. Is there any case law in the world that
4 says the government can't settle it?

5 MR. KLEIMAN: Oh --

6 THE COURT: In fact, you can settle claims beyond
7 what's in the complaint. You don't even have to limit yourself
8 to what's in the complaint.

9 MR. KLEIMAN: Well, the government's position is that
10 what it settled was what was in the Ven-A-Care complaint.
11 There's a --

12 THE COURT: Where does it say that?

13 MR. KLEIMAN: We had communications with DOJ after we
14 saw the settlement come through.

15 THE COURT: I bet you did.

16 MR. KLEIMAN: Yes, and they'll be attached. What they
17 said is, "Look, we settled. What we released," the government
18 says, "is what's in the Ven-A-Care complaint," period.

19 Now, that leaves open the question, what is properly
20 pled in the Ven-A-Care complaint and what is not properly pled?
21 When you look at the standard that this Court has used of
22 conclusory allegations of one broad scheme being inadequate as
23 a basis for pleading, what Ven-A-Care has to say about
24 Recombinate doesn't meet that test.

25 THE COURT: I'd like to see your case law. I believe

1 that the government can, even if it was inadequately pled, that
2 the government can settle it.

3 MR. KLEIMAN: Well, if the government wants to say,
4 "We're settling --" What the government said is, "We're
5 settling based on the covered conduct," and the covered conduct
6 is what's in the complaint. We will be happy to furnish the
7 Court with full briefing on this. I would ask the Court, and I
8 will explain why in a second, for really just two or three
9 extra days. We only heard back from the government about this
10 on Friday of last week.

11 THE COURT: Two or three extra days is fine. It's
12 just, before I write anything up, I mean, on the first-to-file
13 issue, in fact we --

14 MR. KLEIMAN: Well, we'll get there.

15 THE COURT: I think we should argue that because that
16 is fully briefed. But I sort of told everyone to go on hold
17 when I saw this settlement. Now, I don't know whether all
18 drugs includes -- whether there's an argument about Advate, I
19 don't know that, but on Recombinate you've got an uphill
20 battle.

21 MR. KLEIMAN: I recognize that, your Honor, and I'm
22 happy to fight uphill on it.

23 THE COURT: Okay.

24 MR. KLEIMAN: Let me address the motion we have in
25 front of us.

1 THE COURT: Why don't we deal with the first-to-file,
2 and then I'm not sure we need to deal with the cross-
3 subsidization because that's more in the weeds, and I'll wait
4 till I see the brief. And if I don't understand, I'll bring
5 you back in here. But my concern right now is having you spend
6 all this money on briefing if -- in other words, does it make
7 more sense to deal with the release issue first and then have
8 you brief the rest of it later?

9 MR. KLEIMAN: Well, it might make more sense to deal
10 with the release issue first. And we're not opposed to
11 sequencing this. The problem is that if there is a mistake as
12 to fact as to what was and was not encompassed in the release,
13 this means that we're going to have to have discussions with
14 people who were involved in those negotiations on all sides to
15 hash out exactly what was encompassed because there's nothing
16 in that release that suggests that Advate was included. I
17 agree with your Honor that the question about Recombinate is a
18 legal question, but as far as Advate goes, there is nothing
19 other than this very, very slender thread of a labeler code,
20 and the "all drugs" language, which contradicts other language
21 in the release that talks about the covered conduct as in --
22 and specifies the drugs that are listed. So in order to --

23 THE COURT: That may be. That's why I said, I don't
24 know enough about Advate to take the position, but the
25 Recombinate seems -- and I'm happy to have argued the motion,

1 the first-to-file --

2 MR. KLEIMAN: I -- I --

3 THE COURT: We're all up to speed. We're even in
4 draft before we did this. But why don't we do this: Why don't
5 you argue that. I'll wait to see on the first-to-file. And a
6 couple of extra days, will that get you through the
7 cross-subsidization issue as well so that we don't -- I think
8 if you're pretty much done --

9 MR. KLEIMAN: Well, your Honor, to be --

10 THE COURT: I don't want to waste people's money is
11 what I don't want to do.

12 MR. KLEIMAN: To be fully candid, I mean, what we're
13 going to have is a 56(f) declaration saying, here is the
14 discovery we need to unpack this.

15 THE COURT: On Advate, because I'm unlikely to give it
16 on Recombinate.

17 MR. KLEIMAN: Yes, on Advate.

18 MR. JACKSON: Your Honor, if I may and approach, I'd
19 like to hand you the settlement agreement and show you the
20 language. I realize that you're going to wait and see his
21 papers, but the United States' consent is much broader than
22 represented, and I've got them here if you'd like one.

23 THE COURT: I'd love it, and you can hand it up to the
24 Clerk. But in the meantime, let me let your brother here just
25 make his argument, since he's up here prepared, ready to go.

1 Where did you fly in from?

2 MR. KLEIMAN: Los Angeles.

3 THE COURT: You know, beautiful fall New England, but
4 why don't you make your argument on the first-to-file. But I
5 do think I'm trending towards sequencing on the release issue
6 because why go -- I mean, that's a hard issue on this
7 cross-subsidization and what's the record and what isn't the
8 record, and there's a lot of stuff there for you to write up,
9 and for the reply and the surreply and for me to write up, if
10 in fact the release is going to be dispositive one way or
11 another. Anyway, but we'll talk about that later. Go for it
12 on first-to-file.

13 MR. KLEIMAN: Okay. In prior litigation within this
14 MDL, there is a case in which Abbott moved to dismiss a
15 Ven-A-Care complaint and then asked for certification of the
16 issue to the First Circuit. Abbott was taking the position
17 that this Court had used a test saying that the same identical
18 facts had to be in both complaints, and this Court clarified
19 that you need to have the same underlying facts, but they don't
20 have to be exactly the same. What this Court did go on to
21 observe, though, is that what you cannot have are shotgun
22 allegations that basically describe a -- and this is the
23 Court's own words -- a broad scheme and then a bucket list of
24 drugs that fall into that broad scheme.

25 As to Recombinate --

1 THE COURT: Do you have the cite? I've done so many
2 AWP opinions.

3 MR. KLEIMAN: I can get it. It was a June, 2008
4 decision. I've got the Westlaw cite on my computer. I could
5 pull it, or I could furnish it to the Court.

6 THE COURT: You can just provide it to the Clerk later
7 on. I just want to make sure which AWP case you're referring
8 to. There may be forty?

9 MR. KLEIMAN: I know. Yes, this is just a Westlaw
10 cite. There is no official Reporter cite on this. It was from
11 June of 2008, but I'll furnish it to the Court before the end
12 of the day.

13 The Court said specifically -- this is a direct
14 quote -- "The conclusory allegation of one broad scheme is
15 inadequate, particularly in light of the evidence in this MDL
16 demonstrating that each drug must be analyzed differently."
17 The Court then goes on to say that because of that, the
18 plaintiffs have to plead with specificity as to each drug.

19 THE COURT: Is that one of the ones -- that was one
20 where I said that the drug hadn't been listed, so you could
21 bring a separate case involving a brand-new drug.

22 MR. KLEIMAN: Your Honor is correct. That was the
23 erythromycin issue. When you line up the two complaints, what
24 the fourth amended Ven-A-Care complaint says is that there
25 could have been misstatements about list price. We don't know.

1 There could have been misstatements about direct price. We
2 don't know. There could have been misstatements about
3 wholesale net. We don't know. There could have been
4 misstatements about wholesalers' acquisition cost. We don't
5 know. One of these four things happened. Maybe all of the
6 four things happened. Maybe a couple of them happened and a
7 couple didn't. We don't know. That's all we have in the
8 record as to Ven-A-Care's fourth amended complaint.

9 In contrast to that, what we've got in the
10 Sun/Hamilton complaint is something very specific that deals
11 with the non-charge-back wholesalers. Because this is a
12 biologic drug, it has this whole different path of
13 distribution. This is outlined at Paragraphs 27 through 31 or
14 32. In brief, the primary point is that unlike dextrose,
15 unlike lactated ringers, which are the specific items from
16 Baxter that are mentioned in Ven-A-Care's complaint, what we've
17 got is this drug that has this whole other path of distribution
18 where the vast majority of the drug is sold at a price much
19 less than the drug that is sold through the charge-back
20 wholesalers, the McKessons of the world; yet the McKessons of
21 the world form the basis for the reported prices.

22 We have the very specificity this Court said that it
23 wants to see in order to evaluate whether or not something has
24 been properly pled. We have the specificity that allows an
25 actual analysis as to these drugs because of the unique posture

1 of the biologicals. Ven-A-Care does not.

2 We agree that there is a first-to-file question. We
3 think that as to Recombinate, in terms of what is properly
4 pled, which is the only question that's before the Court for
5 the purposes of the motion to dismiss, we have properly pled a
6 false claim as to the misreporting prices for Recombinate; and
7 that it is Ven-A-Care that has indulged in conclusory
8 allegations of a broad scheme; and that if anybody's
9 allegations about Recombinate stand, it is Sun's and Hamilton's
10 and not Ven-A-Care's. That is where we are coming from about
11 this.

12 THE COURT: All right. And so as I understand your
13 basic claim, you would say, "Yes, they've listed the drug, yes,
14 they've listed the broad scheme, but we've provided critical
15 details to understand how it works."

16 MR. KLEIMAN: Very close, your Honor. They have
17 listed four different broad schemes and have never specified
18 which of them, if any, pertain to this drug. They say it could
19 have been this, it could have been that, it could have been
20 something else. They list four broad schemes and say, "Oh,
21 it's one of the four." They never identify which.

22 So if the nature of the scheme matters, there's
23 nothing in Ven-A-Care's complaint that allows us to identify
24 whether they're alleging the same scheme we are. So with that
25 modification, which I think is a crucial one, that comprises my

1 argument.

2 THE COURT: All right, thank you. But before you sit
3 down, how do you want to proceed? It sounds as if you're going
4 to be regardless, be out on Recombinate. So I'm less certain
5 about Advate because it's in the catchall "all drugs." And I
6 don't know. You say there's inconsistent language. I want to
7 see your briefing on it. Would you prefer to brief this all at
8 once, or would you prefer to have me do this sequentially?

9 MR. KLEIMAN: We would rather brief it all at once,
10 but we're going to need -- I mean, the first thing that's going
11 to show up is a 56(f) declaration explaining what it is we need
12 to get at.

13 THE COURT: You only get that if there's an ambiguity.

14 MR. KLEIMAN: I appreciate that, your Honor.

15 THE COURT: So since I have it now in front of me --

16 MR. JACKSON: Your Honor, I marked a couple pages for
17 you. First is the consent of the Justice Department, and
18 that's the second sticker, if you will, and the dismissal with
19 prejudice pursuant to the settlement agreement and release. So
20 it is very broad that the Justice Department has consented.

21 The first tab is Paragraph 2(e) that I mentioned
22 earlier, and I'll direct your attention first to the reporting
23 section. It's the top of Page 3. And this is precisely what
24 the complaint alleges here and precisely what the complaint
25 alleged in Ven-A-Care. It was this providing some kind of

1 price that was inaccurate to the compendia. That created the
2 spread. Spread marketing then occurred. So we think this
3 release is very clear, and I can't imagine that it would be
4 appropriate to undertake discovery of settlement negotiations,
5 so I anticipate that we'll fight that.

6 Then if you look at the drugs, the covered drugs,
7 middle of the page, it's any and all drugs manufactured,
8 marketed, or sold on behalf of any Baxter party; then includes
9 two labeler codes, one of which --

10 THE COURT: Yes, but it says Baxter covered drugs with
11 Labeler Codes 00338. Is that a defined term?

12 MR. JACKSON: It is, your Honor.

13 THE COURT: I wonder what --

14 MR. JACKSON: And, again, if you look at that
15 paragraph, it's all drugs.

16 THE COURT: Yes, I understand your argument from the
17 parenthetical, but I'm just saying, if covered drugs is defined
18 as what's in the complaint --

19 MR. JACKSON: I don't believe it is, your Honor. I
20 believe it's broader than that.

21 THE COURT: It's what?

22 MR. JACKSON: I believe it's broader than that. It's
23 all the Baxter drugs.

24 THE COURT: Where does it say what the definition of
25 "covered drugs" is?

1 MR. JACKSON: If you look at Page 3, your Honor, you
2 have, and I'll read this for the record: "For drugs
3 manufactured, marketed, and/or sold by or on behalf of one or
4 more Baxter parties (any and all drugs manufactured, marketed,
5 and/or sold by or on behalf of any Baxter party, including
6 without limitation --" those in the labeler codes, plus --

7 THE COURT: No, no, that's what you keep reading right
8 over.

9 MR. JACKSON: Well, Your Honor --

10 THE COURT: Excuse me. It says "including, without
11 limitation, Baxter covered drugs with Labeler Codes 00338 and
12 00944." So I'm asking actually a simple question: What is
13 "covered drugs" defined to mean?

14 MR. JACKSON: Keep going. It's the continuation of
15 that sentence. "Covered drugs" is defined as everything I just
16 read.

17 THE COURT: Where?

18 MR. JACKSON: You see the Baxter covered drugs after
19 Labeler Code 00039?

20 THE COURT: I understand, but is there a definition of
21 Baxter covered drugs?

22 MR. JACKSON: Yes, your Honor, right there. That's --

23 THE COURT: That's what you've got?

24 MR. CHEFFO: Yes. That's the definition.

25 THE COURT: There's no definition section or --

1 MR. JACKSON: Your Honor, that's how the parties chose
2 to define covered drugs, to be all of those drugs listed in
3 that clause beforehand.

4 THE COURT: All right, so that's how you're
5 interpreting it.

6 MR. JACKSON: Yes, your Honor.

7 THE COURT: Because typically these complaints that
8 I've been dealing with for a decade refer to covered drugs, and
9 then there's an appendix. You know, there's like a list of a
10 gazillion drugs afterwards. So, in any event, this settlement
11 doesn't go that route?

12 MR. JACKSON: Those settlement agreements I believe,
13 your Honor, were almost entirely in the class cases, and I
14 think that's a different animal because you've got different
15 obligations associated with, you know, non-present --

16 THE COURT: Well, you've probably answered my
17 question. Your answer is, there's no separate definition --

18 MR. JACKSON: Correct.

19 THE COURT: -- or appendix that refers to covered
20 drugs. What I see is what I get right here on Page 3?

21 MR. JACKSON: Yes, your Honor.

22 THE COURT: Okay, perfect. So that's probably going
23 to be the -- but it does say "all drugs." I mean, regardless
24 of what I do with covered drugs and the labeler codes, you've
25 got a problem here.

1 MR. KLEIMAN: We do, your Honor, and at risk of
2 another popular analogy, this is a bit like the --

3 THE COURT: Oh-oh. What if I don't get this one too?

4 MR. KLEIMAN: I'm out on a limb. This is very much
5 like the drunk who's searching for his wallet under the
6 lamppost because that's where the light is rather than in the
7 alley where he lost it. What is missing from my --

8 THE COURT: You're very scenic.

9 MR. KLEIMAN: -- colleague's explanation is that what
10 your Honor will not see anywhere in the settlement agreement
11 and release is the signature of any official from the United
12 States on the settlement and release. They did not sign the
13 settlement agreement. What they have done is say, "We are
14 releasing the claims that Ven-A-Care made in their complaint."

15 THE COURT: Ah-ha, the plot thickens. So you're
16 saying the release --

17 MR. KLEIMAN: The settlement agreement is not signed
18 by the United States. The settlement agreement is signed by
19 Ven-A-Care. The settlement agreement is signed by Baxter. The
20 United States is not a signatory to this agreement and --

21 THE COURT: Does that matter --

22 MR. KLEIMAN: It does matter.

23 THE COURT: -- once they consent to it?

24 MR. KLEIMAN: Well, the question then becomes, to what
25 did they consent? Because the position Baxter is taking here

1 is that Ven-A-Care is able to settle a claim over which this
2 Court had no jurisdiction in the Ven-A-Care case because
3 Ven-A-Care never filed or alleged anything whatsoever about
4 Advate, which would make this a -- this would certainly be a
5 matter of first impression where a relator settles a case for
6 drugs that it never alleged a thing about. The government is
7 held to that release sub silentio, which is basically the
8 position that Baxter is taking here.

9 THE COURT: All right, so that's an interesting
10 preview of the argument, which is -- so let's assume for a
11 minute the release releases everything, but the consent is more
12 limited than that. Is that the legal question?

13 MR. KLEIMAN: Yes, precisely, your Honor. The legal
14 question is, what did the United States intend to consent to
15 the release of? And our understanding is that the United
16 States intended to consent to the release of the claims that
17 Ven-A-Care made in its complaint. What my colleague's
18 recitation --

19 THE COURT: All right, so it's a legal question, so
20 that's what you're going to be briefing.

21 MR. KLEIMAN: Yes.

22 THE COURT: All right. And I do think it makes sense
23 for you to brief everything, and then we'll have the reply and
24 the surreply. But I have to tell you that unless I see
25 something miraculous, Recombinate is not going to survive. And

1 I just hate to waste people's money on it, so I would urge you
2 to have a sort of heart-to-heart internally about whether it's
3 worth preserving the record on it.

4 MR. KLEIMAN: I appreciate that, your Honor. I'm
5 wondering if in light of that, in light of the Court's
6 disposition, it might make sense to address these sequentially
7 rather than doing it in a --

8 THE COURT: You know, you're only three days away from
9 filing it. Just do it.

10 MR. KLEIMAN: Okay.

11 THE COURT: But I have to say, between the
12 first-to-file, which is a strong argument for Baxter, and the
13 release, which is an overwhelming argument for Baxter, I don't
14 want you to waste your money and your time. You may need to do
15 it to preserve the record if you decide you want to appeal, and
16 I'm wondering whether we should just focus on the more
17 complicated issue. But I leave that up to you. You may be
18 finished, so it may not be extra money for you at this point,
19 and I leave that up to you.

20 MR. KLEIMAN: Thank you, your Honor.

21 THE COURT: All right. Yes?

22 MR. JACKSON: Briefly, your Honor, this is a
23 non-intervened case. Ven-A-Care was a non-intervened case.
24 The Justice Department never signs a settlement agreement when
25 they don't intervene. They consent, and that's precisely what

1 happened here. That's what the statute anticipates. So this
2 is the same process that happens on every settlement of every
3 non-intervened case. And I would just direct your attention to
4 the consent because that's how we bind the government is that
5 consent, and it's broader than discussed today.

6 THE COURT: Well, I've reached this issue in other
7 AWP's. You can settle claims beyond the claims in the complaint
8 itself, but when I'm an approving judge in a class action, I
9 want to understand it, and I frequently get objections based on
10 it. And so I don't know if there's case law on it when there's
11 a release of claims that are far broader than are in the
12 complaint and the government signs sort of a broad consent. I
13 just don't know the answer to that. In other words, is that
14 the same as a judge approving it? I just don't know.

15 MR. JACKSON: There is a provision, your Honor, under
16 the statute. When the Justice Department settles a case over
17 the objection of a relator, then there is a situation where the
18 Court decides whether to approve a settlement or not. But the
19 standard for that approval is tiny compared to the normal
20 standard that you're applying to a settlement in the context of
21 a class case.

22 THE COURT: I just don't know. I now understand what
23 the legal question is. You happen to be lucky because you
24 haven't had the -- Uncle Sam, Mr. Bunker Henderson, is sitting
25 back in the courtroom representing the government, so can I ask

1 you, Mr. Henderson -- I've done this to you before, which is
2 horrible to do, but would you want to be heard on this?

3 MR. HENDERSON: Your Honor, I'm not knowledgeable
4 enough to comment on the merits of this. I do have one
5 observation that I bring to the Court's attention, and that is
6 that Baxter has served subpoenas on eleven government carriers
7 for documents, and responding to those would be burdensome. So
8 if there is going to be sequencing of decision-making that may
9 dispose of some of these issues, these carriers should not be
10 required to spend extensive resources responding to the
11 subpoenas.

12 THE COURT: Well, why don't you file an appropriate
13 motion to do that, unless you can get agreement of the parties.
14 There may be some discovery deadline that I'd certainly be
15 willing to hold in abeyance when we work through these. And I
16 understand that you probably don't know, you're not in the
17 weeds of this particular settlement agreement and the consent,
18 but I meant it more broadly. Do you think that the people who
19 are involved in this from the Department of Justice would like
20 to be heard on this issue of what the consent means?

21 MR. HENDERSON: I doubt it, but I can ask.

22 THE COURT: Do we know who it is even?

23 MR. HENDERSON: I believe Mr. Justin Draycott has
24 responsibility for the Baxter litigation.

25 THE COURT: Well, if he should, please have him file

1 a -- I guess it would be either a motion to intervene or simply
2 an amicus brief.

3 MR. HENDERSON: Or a statement of interest.

4 THE COURT: Or a statement of interest, or however it
5 goes, because otherwise I'll do it without the Department of
6 Justice unless I grant the, you know, the 56(f) affidavit.

7 MR. HENDERSON: Very well. And if your Honor does not
8 receive anything, you can assume we will not be filing.

9 THE COURT: All right. Can I ask you this so he
10 doesn't have to waste the taxpayer dollar: Will we agree to
11 stay the subpoenas to the carriers, and I will give you
12 additional time in discovery if such is necessary?

13 MR. JACKSON: Your Honor, we're happy to stay
14 discovery. The one problem that I have is if -- discovery is
15 over theoretically at the end of this month? December 1. To
16 the extent that the relators want to serve discovery, they've
17 waited until it's too late. We served discovery consistent
18 with your prior rulings that if we got it out in a timely
19 fashion, and you stay for a while and then you release and let
20 discovery take place. We're in a position where we should be
21 permitted to continue that discovery if the case continues.

22 THE COURT: Well, you've already got a placeholder.

23 MR. JACKSON: Yes, your Honor. Relators don't, and
24 so --

25 THE COURT: Well, I don't know if they do if it's over

1 December 1. I mean --

2 MR. JACKSON: They filed -- other than some written
3 discovery that we're responding to timely, they have not served
4 discovery on the government, for example, or any of the states,
5 and I don't think it's fair --

6 THE COURT: Well, can I say, I'm not going to jump
7 into the discovery dispute right now. I sort of understand
8 where they're coming from, in that at least -- to spend this
9 kind of money on discovery when I could throw them out, I get
10 it. You're just going to have to do what you're going to have
11 to do. December 1 is the cutoff, and you have to take care of
12 yourself. I don't know when I'm going to rule, if in fact it's
13 continuing. But, you know, I'm not going to start a brand-new
14 discovery period, that's for sure. So you've got a
15 placeholder. I'm not going to cut you off from doing it. I
16 didn't think I was going to back into a whole discovery battle,
17 but I at least want to -- is any of that discovery on
18 Recombinate?

19 MR. JACKSON: I think it's fair to say all the
20 state -- yes, your Honor, and we're okay with that.

21 THE COURT: On the other one, I'm just less certain
22 because of that catchall, and there is some concern I have
23 about these cases, you know. But it may be that they prevail
24 on the, or you prevail, on the merits of the thing if it's in
25 fact as clear as you say it is. But, in any event, I will wait

1 with anticipation the legal briefs, whatever you want to do.
2 And if you decide you don't want to press the Recombinate, let
3 me know. Otherwise, we'll rule on that too. We're pretty far
4 along on the first-to-file issue. It was the settlement that
5 took me by surprise.

6 MR. KLEIMAN: It took us by surprise as well, your
7 Honor. You know, my colleague points out that there is a
8 process by which relators can object to a settlement. That
9 provision of the law assumes that the relators are notified of
10 the settlement. The fact that we never heard a word about it
11 until it was finalized I think is at least --

12 THE COURT: You're not a relator in that case.

13 MR. KLEIMAN: I beg your pardon?

14 THE COURT: You're not a relator in the Ven-A-Care
15 case.

16 MR. KLEIMAN: Yeah, well, that's right, nor is one of
17 our drugs, Advate, part of that case, which is the point we're
18 trying to make.

19 THE COURT: No, I understand, Advate is a different
20 animal. Advate is a different animal. I understand that. So
21 I'm not putting my stake in the ground on Advate, but I am
22 strongly hinting that Recombinate is in trouble.

23 MR. KLEIMAN: The only other thing I would add, your
24 Honor, my colleague is correct about the discovery the relators
25 have and have not gotten out. I am loathe to drag personal

1 matters in here.

2 (Discussion off the record.)

3 MR. KLEIMAN: Thank you, your Honor.

4 THE COURT: He's got a personal problem that's
5 interfered with discovery. You need to, though, take care of
6 it. You can't I go ignore it by filing a motion of some sort
7 or try and work with counsel on the other side to work on
8 what's going on, rather than just let it lapse, okay? All
9 right, I'm sorry about your personal situation which must be
10 very difficult. So why don't I take this under advisement.
11 I'll wait till I get your briefs, and then we'll go from there.

12 Okay, thank you very much.

13 MR. KLEIMAN: Thank you, your Honor.

14 THE CLERK: All rise.

15 (Adjourned, 3:46 p.m.)
16
17
18
19
20
21
22
23
24
25

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court Reporter,
do hereby certify that the foregoing transcript, Pages 1
through 33 inclusive, was recorded by me stenographically at
the time and place aforesaid in Civil Action No. 01-12257-PBS
and 08-11200-PBS, In Re: Pharmaceutical Industry Average
Wholesale Price Litigation, and thereafter by me reduced to
typewriting and is a true and accurate record of the
proceedings.

In witness whereof I have hereunto set my hand this 12th
day of November, 2011.

/s/ Lee A. Marzilli

LEE A. MARZILLI, CRR
OFFICIAL FEDERAL COURT REPORTER